IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

HUMANA, INC., Plaintiff, v. MEDTRONIC SOFAMOR DANEK USA, INC., and MEDTRONIC, INC., Defendants.	Case No. 2:14-cv-02405-JTF-cgc

MEMORANDUM OF LAW IN SUPPORT OF
MEDTRONIC SOFAMOR DANEK USA, INC.'S, AND MEDTRONIC, INC.'S
MOTION TO DISMISS HUMANA INC.'S FIRST AMENDED COMPLAINT

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Defendants Medtronic Sofamor Danek USA, Inc., and Medtronic, Inc. (collectively, "Medtronic"), respectfully submit this memorandum of law in support of their motion, pursuant to Federal Rules of Civil Procedure 8, 9(b), 12(b)(1), and 12(b)(6), to dismiss all counts of Humana, Inc.'s First Amended Complaint ("FAC") with prejudice.

PRELIMINARY STATEMENT

In an attempt to cure the deficiencies of its original complaint, Humana tries to repackage its old claims and tacks on a few new ones. But these changes cannot disguise Humana's continued inability to plead an injury traceable to Medtronic. In the hope of closing this causation gap, Humana now concedes that it willingly reimbursed hospitals and other providers for off-label uses of Medtronic's Infuse device.[1] It no longer questions those providers' independent medical judgment that the procedures were appropriate. Instead, Humana alleges that it only agreed to pay for the procedures because Medtronic purportedly caused misleading statements to be made regarding their safety and effectiveness. The result is a sprawling 90-page amended pleading consisting principally of publicly available information and a kitchen sink set of tenuously related claims that fail for at least three reasons:

First, an insurance company that pays for medically necessary, covered procedures is not suffering an "injury"—it is carrying out its basic function. In order to plead an injury-in-fact traceable to some fraud on Medtronic's part, Humana would have to show (1) that the Infuse device did not perform as expected for a patient insured by Humana; and (2) that, as a result, Humana was forced to pay additional treatment costs over and above the expected costs associated with the known and disclosed risks of the Infuse procedure. But Humana does not make a single specific allegation that Infuse was unsafe or ineffective when used in any of its

[1] "Infuse" refers to Infuse Bone Graft/LT-CAGE Lumbar Tapered Fusion Device, a Class III medical device manufactured by Medtronic and approved by the FDA through PMA Number P000058 and all supplements thereto, more fully described, *infra* at p. 3.

insureds. Indeed, after two attempts, and despite having all of the reimbursement records in its possession, Humana fails to identify a *single* insured who suffered an Infuse-related injury. That failure leaves Humana in the untenable position of asking this Court to retroactively provide it with free prescription medical devices at Medtronic's expense, even though it paid for them, as insurance companies do, with premiums collected from its insureds. Humana is not entitled to such a windfall.

Second, the vast majority of Humana's claims are time-barred. Humana now admits that it began to question the safety and effectiveness of off-label uses of Infuse in late 2008, when, according to Humana, publicly available studies reported greater potential risks than previous studies, and national newspapers ran stories suggesting that Medtronic had influenced the earlier research. Indeed, the public controversy surrounding Infuse led Humana to adopt a policy in early 2009 barring reimbursement for off-label procedures. This internal determination renders implausible Humana's claim that it continued to reasonably rely on pre-2008 studies in making reimbursement decisions. As a result, the limitations periods applicable to most of its claims expired well before it filed its original complaint.

Third, those of Humana's fourteen counts not categorically barred by its inability to plead injury, causation, reliance, or timeliness, fail for other reasons. Humana's speculative allegations of fraudulent claims for reimbursement fail to satisfy the particularity requirements of Rule 9(b). Its attempts to plead a violation of every consumer protection act in the country without elaboration violate the basic tenets of notice pleading and procedural fairness. And its premature effort to obtain indemnification from insureds who might settle personal injury claims with Medtronic is not supported either by statute or caselaw.

BACKGROUND[2]

Medtronic manufactures an FDA-approved Class III medical device called the Infuse Bone Graft/LT-CAGE Lumbar Tapered Fusion Device ("Infuse"). Infuse is a prescription medical device that comprises two components: (1) a two-part bone graft component, which comprises recombinant human bone morphogenetic protein-2 ("BMP") and an absorbable collagen sponge ("ACS"); and (2) the LT-Cage Lumbar Tapered Fusion Device ("LT-Cage"). The FAC alleges that Medtronic promoted—and Humana knowingly reimbursed for—the use of Infuse in a manner not specified on the device label. FAC ¶¶ 30–38, 145.

The FDA does not regulate the use of medical devices and is generally prohibited from "limit[ing] or interfer[ing] with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease." 21 U.S.C. § 396; *see* FDA, *Use of Approved Drugs for Unlabeled Indications*, 12 FDA Drug Bull. 4, 5 (1982). It was therefore neither illegal nor improper for practitioners to use Infuse in off-label applications and claim reimbursement from Humana. Humana does not allege otherwise. Instead, Humana claims that it agreed to reimburse for off-label procedures, beginning in 2002, in reliance on medical literature that purportedly understated the risks and overstated the effectiveness of BMP. *See* FAC ¶¶ 146–61. That literature, Humana claims, was manufactured by and for Medtronic in order to deceive insurers. *Id.* ¶¶ 155–56; *see* ¶¶ 40–139. Humana alleges that it has spent "millions of dollars" on off-label Infuse procedures since 2002, *id.* ¶ 187, and unspecified sums on treatment for purported Infuse-related injuries, *id.* ¶¶ 10, 292, 307. The Complaint identifies just twelve claims, paid from May 2008 to April 2012, without indicating the procedures to which those claims pertain, or the particular allegations they are meant to substantiate. *See id.* ¶¶ 188, 266.

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[2] The following recitation is based on the allegations in the FAC, which Medtronic is required to accept for the purposes of this Motion to Dismiss only.

According to the FAC, in late 2008, Humana became aware of new evidence suggesting that Infuse was not as safe in off-label applications as previously believed. *Id.* ¶ 162. In response, it adopted a policy in February 2009 prohibiting reimbursement for such uses. *Id.* But Humana claims that it nevertheless continued to reimburse for off-label Infuse procedures on a case-by-case basis in reliance on the same literature it had already concluded was unreliable. *Id.* ¶ 165. Humana further alleges that Medtronic representatives induced it to rely on this purportedly misleading literature when they cited it during a 2010 meeting at Humana's headquarters. *Id.* ¶¶ 166–73.

Humana separately alleges that it unknowingly paid for off-label uses of Infuse as a result of misleading or incomplete claims filed by providers with Medtronic's connivance. *See id.* ¶¶ 176–81. In particular, Humana asserts that Medtronic discouraged providers from supplying documentation that would have revealed off-label uses, *id.* ¶ 178, and encouraged the use of incomplete or misleading billing codes. *Id.* ¶ 181. Finally, Humana alleges that Medtronic has settled product liability claims related to Infuse with "[a]t least one (and likely more)" of its insureds. *Id.* ¶ 350. Humana claims that it is entitled under the Medicare statute to reimbursement for any Medicare benefits it advanced to that individual (or those individuals) for the treatment of the "injuries or illnesses" allegedly caused by Infuse. *Id.* ¶¶ 348, 352–55.

ARGUMENT

I. HUMANA FAILS TO ALLEGE ANY INJURY IN FACT.

At the heart of Humana's amended complaint is the charge that Medtronic's alleged influence over the medical literature regarding BMP and Infuse caused Humana to pay for off-label Infuse procedures when other, purportedly better treatment options were available. FAC

¶¶ 8, 10. Humana alleges further that Infuse's supposed ineffectiveness "may have" necessitated "revision surgeries" or other follow-on procedures paid for by Humana. *Id.* ¶ 189; *see* ¶¶ 10, 292, 307–08. But the Complaint falls short of the "irreducible constitutional minimum of standing" in two respects: it fails to allege either an "injury in fact" or a "fairly traceable connection between [Humana's] injury and the complained-of conduct" of Medtronic. *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 103 (1998) (internal quotation marks omitted). These defects are jurisdictional in nature, and are fatal to Humana's common law, RICO, subrogation, warranty, consumer protection, unjust enrichment and conversion claims. *See, e.g.*, *In re Carter*, 553 F.3d 979, 984 (6th Cir. 2009) (challenge to Article III standing is jurisdictional); Fed. R. Civ. P. 12(b)(1).

A. Humana Lacks Standing to Bring Any Claims Based on Alleged Misrepresentations of Infuse's Safety and Effectiveness (Counts One–Four and Six).

1. Reimbursement for Off-Label Infuse Procedures Does Not Constitute an Injury in Fact.

An "injury in fact" is the "invasion of a legally protected interest." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). Reimbursing patients and providers for medically necessary and covered procedures cannot, standing alone, constitute an invasion of Humana's "legally protected interest[s]." Such reimbursements are part of the "conscious bargain" insurance companies make with their insureds, for which they are duly compensated through premium payments. *Ironworkers Local Union 68 v. AstraZeneca Pharms., LP*, 634 F.3d 1352, 1365 (11th Cir. 2011). Humana cannot transform these payments into "economic injuries" merely by alleging that off-label Infuse procedures are less safe than originally reported. The injury-in-fact "test requires more than an injury to a cognizable interest. It requires that the party seeking review be himself among the injured." *Lujan*, 504 U.S. at 563 (internal quotation marks omitted); *see Sierra Club v. Morton*, 405 U.S. 727, 734–35 (1972). To show some injury to itself, Humana would have to plausibly allege, at the very least, (1) that it was forced to pay for treatments made necessary by the off-label use of Infuse on its insureds, and (2) that the cost of those procedures was greater than the cost of dealing with the unavoidable risks inherent in any medical procedure. *See Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 319–21 (5th Cir. 2002) (plaintiff failed to establish standing when she could not allege that she suffered an actual injury as a result of taking an allegedly defective drug). To contend otherwise would be to argue that Humana is entitled to free prescription medical devices simply because BMP may, as a statistical matter, have performed differently than it expected. Again, the FAC does not even make specific allegations that Infuse did not work as intended for any patient insured by Humana.

To the extent Humana alleges an injury on the alternative theory that the Infuse procedures it paid for were more expensive than the available alternatives, it fails to trace any resulting injury to Medtronic. Despite its attempts to bury the role of doctors' independent medical judgment under its allegations of fraud, Humana cannot plead around the facts. Having elected to provide coverage for off-label uses of Infuse from 2002-2009, *see* FAC ¶¶ 145, 164, Humana reserved the selection of one form of treatment over another to the medical judgment of providers.[3] *See id.* ¶ 142 ("[T]he treating physician elects to use BMP in a particular procedure."). As Humana repeatedly avers, doctors chose off-label Infuse procedures from a range of options that included autografts (uses of the patient's own bone matter) and allografts (grafts based on cadaveric or donated bone matter), among others.[4] *E.g.*, *id.* ¶¶ 10, 42, 51.

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[3] Humana alleges that it "generally requires pre-approval" for the procedures at issue in this case, FAC ¶ 141, but it does not allege that Humana constrains physicians' discretion to select the form of treatment that comports with their independent medical judgment.

[4] Each of these approaches has its own costs and risks; Humana does not allege that the actual Infuse procedures performed on its insureds were any more likely to fail than alternative

Medtronic's alleged promotion of its own product for these uses would therefore have been just one of many factors—presumably including marketing by Medtronic's competitors and doctors' individualized assessments of patients' medical histories, conditions, and risk profiles—that influenced the ultimate selection of Infuse procedures for Humana's insureds.

Where standing "depends on the unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion courts cannot presume either to control or predict," the plaintiff must "adduce facts showing that those choices have been . . . made in such a manner as to produce causation." *Lujan*, 504 U.S. at 562 (internal quotation marks omitted). A viable complaint would therefore have to plausibly allege, among other things, both that doctors would not have prescribed, and patients would not have agreed to be treated with, Infuse but for Medtronic's conduct, *and* that the selection of Infuse resulted in higher costs to Humana in the aggregate. *See Rivera*, 283 F.3d at 321; *Ironworkers Local*, 634 F.3d at 1363–64. The FAC does not. [5]

Even if doctors' exercise of their independent medical judgment does not sink Humana's fraud claims, its allegations that Infuse procedures cost more than appropriate alternatives are no more than "naked assertions devoid of further factual enhancement" not entitled to a presumption of truth. *Iqbal*, 129 S. Ct. at 1949 (internal quotation marks omitted). Indeed, since Humana is in the business of making coverage determinations, its failure to do more than vaguely allege the existence of "less expensive" alternatives, FAC ¶ 10, is especially notable.

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treatments, or that the costs of remediating any complications were higher for insureds who underwent Infuse procedures than for those treated with other procedures.

[5] Humana obliquely suggests that some of the providers who provided Infuse treatments to its insureds were agents or co-conspirators of Medtronic. *See id.* ¶ 141. That naked assertion, which is not entitled to a presumption of truth, *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009), makes it even harder to understand why Humana is unable to identify a single claim it paid from 2002–2008. After all, if Humana can identify the individual doctors involved in submitting the claims, it should be capable of pleading the claims themselves.

See Bishop v. Lucent Techs., Inc., 520 F.3d 516, 522 (6th Cir. 2008) ("The court should not assume facts that could and should have been pled, but were not.").

2. The Complaint Fails to Plausibly Allege Any Reimbursements Necessitated by Infuse-Related Injuries.

Humana's allegations that it paid for treatments necessitated by Infuse-related injuries are conclusory at best. The FAC pleads variously that claimants "may" have been injured as a result of off-label Infuse procedures, *id.* ¶ 189, and that Humana's damages "include" expenses related to the treatment of Infuse-related injuries. *Id.* ¶ 292; *see id.* ¶¶ 307–08. Yet despite having possession of all the treatment and reimbursement records necessary to substantiate these allegations, Humana fails to identify a single actual injury suffered or additional treatment made necessary by the off-label use of Infuse. A plaintiff with actual knowledge of the true facts is not entitled to have ambiguities in the complaint resolved in its favor. *See Bishop*, 520 F.3d at 522 & n.1. And even if Humana could show some record of reimbursements, it has failed to allege that any Infuse-related costs were greater than costs associated with the unavoidable risks inherent in any medical procedure. Nor has it alleged that they were inconsistent with the unavoidable risks associated with Infuse, which were plainly stated on the device label.[6] "[S]tanding cannot be inferred from averments in the pleadings." *White v. United States*, 601 F.3d 545, 551–52 (6th Cir. 2010). Humana's "naked assertions devoid of further factual enhancement" cannot establish an injury in fact for standing purposes. *Id.* at 552 (quoting *Iqbal*, 129 S. Ct. at 1949).

3. Humana Lacks Standing to Bring Its Consumer Protection Claims.

Humana's statutory consumer protection claim appears to be little more than a repackaged fraud claim. *See* FAC ¶¶ 297–98. Because Humana makes no effort to connect any

[6] *See* Ex. 1.

of Medtronic's alleged conduct with a violation of any of the consumer protection statutes it cites, Medtronic can only guess at the substance of its purported consumer protection violations.[7] Assuming, without conceding, that Humana's consumer protection claim is predicated on the same injuries as its fraud-based claims, it must fail for the reasons described above.

B. *With No Plausible Allegation of Injury to Any Insured, Humana's Subrogation and Warranty Claims Must Also Fail (Counts Five, Seven and Eight).*

1. Subrogation

As an initial matter, Humana does not have standing to pursue a subrogation claim here. Subrogation "simply means" that "one person is allowed to stand in the shoes of another and assert that person's rights against a third party." *US Airways, Inc. v. McCutchen*, 133 S. Ct. 1537, 1546 n.5 (2013) (internal quotation marks omitted). A patient does not establish standing by alleging no more than that she underwent a medical procedure that might have—but did not—injure her. *See Rivera*, 283 F.3d at 319–21. And where its subrogors have no standing, neither does Humana. *See Homestake-Sapin Partners v. United States*, 375 F.2d 507, 509 (10th Cir. 1967) (explaining that a "subrogee [can]not rise above the rights of its subrogor").

Even if Humana had standing to bring its subrogation claims, its pleading is wholly deficient. "[T]o proceed as subrogees," insurers "must identify the persons to whose claims the insurers are subrogated and show that the insureds are entitled to recover, that the plaintiffs have a contractual right to proceed on each insured's behalf with respect to each claim, and that the suits fall within federal jurisdiction." *Health Care Serv. Corp. v. Brown & Williamson Tobacco Corp.*, 208 F.3d 579, 581 (7th Cir. 2000); *Blue Cross & Blue Shield of N.J., Inc. v. Philip Morris*

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[7] As described in Part III.B, *infra*, Humana's failure to satisfy the requirements of notice pleading with respect to its consumer protection claim constitutes an independent ground for the dismissal of Count Six.

USA Inc., 344 F.3d 211, 218 (2d Cir. 2003) (stating that a failure to provide individualized information about subrogated claims is "clearly contrary to the common law understanding of the nature of subrogation claims"). Humana makes no attempt to meet this threshold requirement. The FAC, devoid of any allegations of injuries to identifiable Humana health plan members, leaves Medtronic in the untenable position of having to guess whether there are, in fact, any claims to defend.[8] And the FAC's insufficiency is all the more stark when considered in light of the fact that Humana is the *only* party in possession of the information necessary to provide a complete picture of its putative subrogated causes of action.

2. Express and Implied Warranties

Humana's warranty claims likewise depend on the premise that off-label uses of Infuse caused some injury to its insureds. FAC ¶¶ 307, 312 (describing damages as "health care costs related to BMP . . . that are the responsibility of [Medtronic]"). Any action brought in Tennessee on the basis of "harm caused by a product" is covered by the state's Products Liability Act (the "TPLA"), "regardless of the legal theory advanced." *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378, 392, 402 (6th Cir. 2013); Tenn. Code Ann. § 29-28-102(6). A "threshold requirement of a Tennessee products-liability claim" is that "the plaintiff assert that the defendant's product caused the plaintiff's injury." *Strayhorn*, 737 F.3d at 401 (internal quotation marks omitted).

In *Rivera*, the Fifth Circuit rejected a products liability claim with the same defects presented by Humana's FAC. The plaintiffs in that case alleged that the defendant pharmaceutical company had breached an implied warranty of merchantability by selling a drug that was ultimately withdrawn from the market because of its potential to cause liver failure. 283

[8] If they existed, any subrogated claims would be subject to a range of defenses, including, but not limited to, the statutes of limitation and repose, the learned intermediary doctrine, and the preemption of medical device-related products liability claims under the Food, Drug, and Cosmetic Act ("FDCA"), *see* 21 U.S.C. § 360k(a); *Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1203 (8th Cir. 2010).

F.3d at 317. But the plaintiffs did not claim that the drug was ineffective or harmful to *them*. *Id.* at 319. Instead, they argued that they were injured because they paid for a defective drug. *Id.* at 319–20. The Fifth Circuit dismissed the case for failing to establish an injury in fact. *Id.* at 320. The court concluded that it was "not enough" to show that "[the defendant] may have violated a legal duty owed to some other patients. . . . What courts require is that the injury be personal." *Id.* (alteration and internal quotation marks omitted). Humana may not "borrow" injuries from subjects of clinical trials who experienced complications related to BMP. And because Tennessee does not allow products liability plaintiffs to recover for purely economic losses, Humana could not establish injury even if it could show that its insureds received ineffective Infuse procedures. *See Lincoln Gen. Ins. Co. v. Detroit Diesel Corp.*, 293 S.W.3d 487, 489, 491–93 (Tenn. 2009). Because there is no allegation that Infuse caused injuries for which Humana was required to pay, Humana suffered no injury.[9]

C. Because Humana's Insureds Actually Underwent Infuse Procedures, Humana Cannot Maintain its Claims for Unjust Enrichment or Conversion (Counts Nine and Ten).

1. Unjust Enrichment

"The most significant requirement of an unjust enrichment claim is that the benefit to the defendant be unjust." *Freeman Indus., LLC v. Eastman Chem. Co.*, 172 S.W.3d 512, 525 (Tenn. 2005). The law in Tennessee is clear that when the defendant has provided consideration in exchange for the benefit conferred, it is *not unjust* to retain the benefit, and the claim must be dismissed as a matter of law. *Whitehaven Cmty. Baptist Church v. Holloway*, 973 S.W.2d 592, 597 (Tenn. 1998). The FAC reveals that Humana received consideration in exchange for the "benefit" of its reimbursement payments—its insureds actually underwent surgeries using Infuse.

[9] Even if Humana could show that Infuse actually caused any injury, Medtronic's liability would be limited, under state law, by its categorical disclaimer of all warranties, *see* Ex. 1 and, under federal law, by both express and implied preemption. *See, e.g.*, *Bryant*, 623 F.3d at 1203.

Many of those surgeries undoubtedly resulted in positive health outcomes for the patients. Moreover, a plaintiff alleging unjust enrichment on the basis of purchases of the defendant's product from a third party "must further demonstrate that he or she has exhausted all remedies against the person with whom the plaintiff enjoyed privity of contract"—in this case, the *providers* who actually billed Humana. *Freeman Indus.*, 172 S.W.3d at 525. The FAC includes no allegation that Humana has sought a remedy from those providers, and no claim that it would be futile to do so. *See id.* at 526.

2. Conversion

Humana's related conversion claim is incoherent. "Conversion is the appropriation of another's property to one's own use and benefit, by the exercise of dominion over the property, in defiance of the owner's right to the property." *Ralston v. Hobbs*, 306 S.W.3d 213, 221 (Tenn. Ct. App. 2009). In this case, Humana paid providers in satisfaction of their claims for reimbursement for treatment they provided. Medtronic simply has nothing to do with that relationship. Moreover, money is generally not subject to a claim of conversion unless it is "specific and capable of identification or where there is a determinate sum that the defendant was entrusted to apply to a certain purpose." *PNC Multifamily Capital Institutional Fund XXVI Ltd. P'ship v. Bluff City Cmty. Dev. Corp.*, 387 S.W.3d 525, 553 (Tenn. Ct. App. 2012). Where that is the case, conversion "will lie" only as long as the money was "converted without the plaintiff's express or implied assent that the relation of debtor and creditor should arise." *Id*. And if the conversion is alleged to be intentional, Tennessee courts apply heightened pleading standards. *See id.* at 555.

Humana's claims would have to be dismissed under any standard because not only do they fail to identify the amounts at issue, *id*. at 553, but because Humana explicitly "assent[ed] that the relation of debtor and creditor should arise," *id.*, when it paid *providers* on the basis of valid claims for reimbursement.

II. MOST OF HUMANA'S CLAIMS ARE TIME-BARRED.

Federal courts sitting in diversity jurisdiction apply the substantive law of the forum state, including its statutes of limitation. *See Guar. Trust Co. of N.Y. v. York*, 326 U.S. 99, 108–09 (1945). Because Humana fails to specify any injury, let alone where the injury occurred, Medtronic assumes for the purposes of this motion to dismiss that Humana's common law and consumer protection claims are subject to the limits applicable in Tennessee courts.[10] Civil RICO claims are subject to a federal statute of limitations. *Rotella v. Wood*, 528 U.S. 549, 552 (2000).

Different rules govern the accrual of the various claims asserted in the FAC. The simplest of these pertain to Humana's conversion claim. Although Tennessee courts have not explicitly addressed the accrual of claims based on the conversion of money, a claim for conversion of a negotiable instrument accrues "when the instrument is negotiated." *Pero's Steak & Spaghetti House v. Lee*, 90 S.W.3d 614, 624 (Tenn. 2002). By analogy, a claim for converted cash should accrue at the time the cash is misappropriated.

Humana's other common law tort claims and its subrogation claims—which are based on tort claims—are subject to Tennessee's "discovery rule." The discovery rule "tolls the running of the statute of limitations until the plaintiff knows, or in the exercise of reasonable diligence, should know that an injury has been sustained." *Id.* at 621. The rule "charges a plaintiff with knowledge of those facts that a reasonable investigation would have disclosed." *Redwing v. Catholic Bishops for Dioc. of Memphis*, 363 S.W.3d 436, 459 (Tenn. 2012). "Once a plaintiff gains information sufficient to alert a reasonable person of the need to investigate the injury, the limitation period begins to run." *Id.* (internal alterations and quotation marks omitted).

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[10] To the extent Humana's subsidiaries are domiciled in states with a shorter limitations period that has already run, they are barred under Tennessee's "borrowing statute." Tenn. Code Ann. § 28-1-112. Humana's failure to satisfy the basic pleading requirements set forth in Federal Rules of Civil Procedure 8(a) and 9(b) makes it impossible to determine with certainty which state's laws would govern its various claims (and is reason enough to dismiss the FAC). To the extent the statutes of limitation of any other state would bar any of Humana's claims, Medtronic reserves its right to assert them if it becomes apparent that any of Humana's claims are subject to the laws of those other states.

Likewise, a RICO claim accrues "as soon as the plaintiff discovers, or reasonably should have discovered, both the existence and source of his injury and that the injury is part of a pattern." *Isaak v. Trumbull Sav. & Loan Co.*, 169 F.3d 390, 399 (6th Cir. 1999). In the Sixth Circuit, "[t]he plaintiff need only possess a low level of awareness . . . . [T]he clock begins to tick when a plaintiff senses 'storm warnings,' not when he hears thunder and sees lightning." *Isaak*, 169 F.3d at 399; *see Koch v. Christie's Int'l PLC*, 699 F.3d 141, 153 (2d Cir. 2012) (explaining that "numerous articles" on the general subject matter constituted storm warnings in a RICO case).

Humana filed its original complaint on May 31, 2014. The table below sets forth the applicable limitations periods, and the earliest dates on which a cause of action could have accrued in order to be timely asserted in the original complaint; any cause of action that accrued earlier is, of course, time-barred:

Count(s)	**Claim(s)**	**Limitations Period**	**Earliest Date Claim Could Have Accrued and Still Be Timely**	**Source**
One, Four, Nine, Ten	Fraudulent Misrepresentation, Concealment, Omission, and Fraud in the Inducement; and Negligent Misrepresentation; Unjust Enrichment; Conversion	3 years	May 31, 2011	Tenn. Code Ann. § 28-3-105
Two, Three	RICO; RICO Conspiracy	4 years	May 31, 2010	*Rotella*, 528 U.S. at 552
Five, Seven, Eight	Subrogated Personal Injury Claims;[11] Breach of Express and Implied Warranties[12]	1 year	May 31, 2013	Tenn. Code Ann. § 28-3-104
Six	Consumer Protection Act	1 year	May 31, 2013	Tenn. Code Ann. § 47-18-110

A. Humana Was on Inquiry Notice of Medtronic's Alleged Conduct No Later than Mid-2009.

The FAC and public record show that Humana was, at a minimum, on inquiry notice of most of the claims asserted here long before filing its original complaint.[13] The purported financial links between Medtronic and leading spine surgeons described in the FAC were the subject of widely disseminated reports no later than 2008.

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[11] Tennessee courts "look to the basis for which the damages are sought" to determine which statute of limitation applies. *Tip's Package Store, Inc. v. Commercial Ins. Managers, Inc.*, 86 S.W.3d 543, 551 (Tenn. Ct. App. 2001). Where, as here, a claim is asserted on behalf of a subrogee for personal injuries, *see* FAC ¶ 292, the statute limiting personal injury actions applies. *See Ind. Lumbermens Mut. Ins. Co. v. State Farm Mut. Auto. Ins. Co.*, 511 S.W.2d 713, 715 (Tenn. Ct. App. 1972).

[12] *See Tip's Package Store*, 86 S.W.3d at 551; *Strayhorn*, 737 F.3d at 392 (claims predicated on a product-related personal injury are subject to the TPLA, even if phrased as warranty claims).

[13] In assessing the evidence of Humana's knowledge, this Court may consider any document "referred to in the pleadings and . . . integral to the claims" and any "matters of public record" "without converting a motion to dismiss into one for summary judgment." *Commercial Money Ctr., Inc. v. Ill. Union Ins. Co.*, 508 F.3d 327, 335–36 (6th Cir. 2007).

In September 2008, a front-page article in the *Wall Street Journal* reported that "[d]octors with financial relationships with Medtronic have written favorably about off-label uses of Infuse on Web sites, in medical journals and at educational meetings."[14] The article reported that Infuse had been "linked to life-threatening complications in dozens of patients" and cited an FDA notification cautioning doctors about off-label uses of the device.[15]

Just a few months later, in February 2009, Humana issued a policy (the "BMP Policy") barring reimbursement for all off-label uses of Infuse.[16] FAC ¶ 162. Incredibly, Humana maintains that it adopted that policy without regard to the contemporaneous news coverage linking favorable studies on BMP and payments to their authors by Medtronic. *E.g.*, *id.* ¶ 239. But "[t]he rule in this Circuit is that where events receive widespread publicity, plaintiffs may be charged with knowledge of their occurrence . . . even when she claims that she did not hear or read any of the media reports." *Ball v. Union Carbide Corp.*, 385 F.3d 713, 722 (6th Cir. 2004) (alterations, internal citations, and quotation marks omitted) (applying Tennessee law).

The front-page coverage in the *Wall Street Journal* was enough to spur any reasonable company (and certainly a major health insurance company) to investigate its reliance on BMP-related research.[17] Indeed, Humana promulgated the BMP Policy "based upon the balance of the literature (which then included more recent non-fraudulent articles *exposing the dangers and inefficacy* of highly expensive, off-label BMP uses) . . . ." FAC ¶ 163 (emphasis added).

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[14] *See* Ex. 2 (David Armstrong and Thomas M. Burton, *Medtronic Product Linked to Surgery Problems*, Wall St. J., Sept. 4, 2008). The FDA notification, dated July 1, 2008, is available at: http://goo.gl/HVCmS.

[15] *Id.*

[16] *See* Ex. 3 (Recombinant Bone Morphogenetic Proteins, Medical Coverage Policy, Policy No.: CPD–0479–001).

[17] The article caught the attention of Senator Charles Grassley, who wrote to Medtronic with a series of questions related to its alleged payments to doctors in connection with the promotion of Infuse. *See* Ex. 4 (Letter from Sen. C. Grassley to B. Hawkins, President and CEO, Medtronic, Inc. (Sept. 30, 2008), available at: http://goo.gl/TlkLsI).

Humana claims it never suspected Medtronic's alleged role. But to the extent the early medical literature was inconsistent with later studies, Humana actually knew that by February 2009. In response, Humana stopped relying on the earlier research, and repeatedly reaffirmed that decision in annual reviews of the BMP Policy. *See id.* ¶¶ 162–65. When a plaintiff's duty to inquire is triggered, but its investigation fails to uncover any injury, the statute of limitations is tolled until the date "a reasonably diligent investigation would have revealed the injury to a person of reasonable intelligence." *See Koch*, 699 F.3d at 153. That date must have arrived prior to Humana's adoption of the BMP Policy in February 2009. In fact, in January 2009, the *Wall Street Journal* reported that Dr. Thomas Zdeblick—whose alleged activities on behalf of Medtronic are reviewed in the Complaint, *see* ¶¶ 91–95—had been paid $19 million by Medtronic from 2003 to 2007.[18]

Additional information about alleged payments by Medtronic to doctors streamed into the public domain even after Humana implemented the BMP Policy. In May 2009, the *New York Times* reported that a former doctor at the Walter Reed Army Medical Center, identified as a paid consultant for Medtronic, had falsified the results of a study regarding the effectiveness of BMP.[19] The *Times* reported that the same doctor had given talks promoting Infuse to other surgeons, and that the challenged study was retracted by the *Journal of Bone and Joint Surgery* at the request of Walter Reed officials. These reports were followed in July 2009 with allegations that another doctor had accepted payments from Medtronic around the time the

[18] *See* Ex. 5 (David Armstrong and Thomas M. Burton, *Medtronic Paid Researcher More than $20,000—Much More*, Wall St. J., Jan. 16, 2009). *See also*, John Fauber, *Medical Device Maker Paid UW Surgeon $19 Million*, Wisc. J. Sentinel, Jan. 16, 2009.

[19] *See* Ex. 6 (Duff Wilson and Barry Meier, *Doctor Falsified Study on Injured G.I.'s, Army Says*, N.Y. Times, May 12, 2009. *See also id.*, *Senator Seeks Data on Doctor Accused by Army of Falsifying a Product Study*, N.Y. Times, May 18, 2009). The online version of the latter article attached a series of letters from Sen. Grassley detailing the alleged misconduct. Available at: http://goo.gl/cKUxg7.

Department of Defense gave him a grant to study Infuse.[20] This cascade of allegations, published in major national newspapers, surely put Humana on notice that the purported divergence between results reported in earlier studies and those reported in later studies might be attributable to the conduct alleged in the FAC rather than mere "errors of the physician authors." FAC ¶ 239.

Humana's allegation that the public reports did not detail the extent or means of Medtronic's alleged influence over the medical literature on BMP does not salvage its claims. The discovery rule does not toll a limitations period until the plaintiff has discovered "all the facts that affect the merits of his or her claim." *Redwing*, 363 S.W.3d at 459. These revelations were undoubtedly "sufficient to alert a reasonable person of the need to investigate the injury." *Id.* (internal quotation marks omitted). With respect to Humana's RICO claims, the articles cited above were far more than the mere "storm warnings" necessary to start the statutory clock. *Isaak*, 169 F.3d at 399; *see Koch*, 699 F.3d at 153; *Prudential Ins. Co. of Am. v. U.S. Gypsum Co.*, 359 F.3d 226, 238 (3d Cir. 2004). Under the circumstances, Humana must be charged with actual or constructive knowledge of what everybody was being told in the fall of 2009: Medtronic had financial relationships with doctors who authored articles concerning the efficacy of Infuse and BMP.[21]

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[20] *See* Ex. 7 (David Armstrong and Thomas M. Burton, *Spine Surgeon Didn't Disclose Medtronic Pay in Testimony*, Wall St. J., Jul. 29, 2009). The online version of the article linked to a 142-page set of documents compiled by Senator Grassley and documenting in detail the financial links between Medtronic and the doctor in question. Available at: http://goo.gl/y0YkVW. The same doctor was mentioned in a story published the same day in the *New York Times*. Barry Meier, *2nd Medtronic Consultant Draws Senate's Scrutiny*, N.Y. Times, Jul. 29, 2009.

[21] Medtronic denies the existence of any *quid pro quo* relationship between the physicians involved and the company. To the extent any compensation was provided, doctors were compensated for work unrelated to promoting Infuse, including their contributions to the invention or development of Medtronic products. Humana's allegations to the contrary are false and are recited here only for the purposes of this Motion to Dismiss.

B. Humana's Allegations of Fraudulent Concealment Are Wholly Conclusory.

The public record shows why Humana cannot invoke fraudulent concealment to toll the statutes of limitation. A plaintiff invoking that doctrine must adequately allege and ultimately be able to "demonstrate that [it] exercised reasonable care and diligence in pursuing [its] claim." *Redwing*, 363 S.W.3d at 463. Humana's only effort to satisfy that threshold requirement is the conclusory allegation that it "has been kept in ignorance of vital information essential to the pursuit of [its] claims, without any fault or lack of diligence on Humana's part." FAC ¶ 238. But "what matters" in a claim of fraudulent concealment "is that the defendant has taken steps to prevent the plaintiff from discovering he was injured." *Fahrner v. SW Mfg., Inc.*, 48 S.W.3d 141, 146 (Tenn. 2001). Humana has alleged nothing more than the underlying fraud itself; it has failed to allege that Medtronic "took steps" to prevent it from discovering its injury.

To the extent Humana attempts to shore up these deficiencies by alleging that Medtronic's representatives had a duty to disclose the company's alleged relationship with researchers at an October 2010 meeting with Humana, it falls flat. *See* FAC ¶¶ 166–75. Even if Medtronic's representatives had some duty to disclose that the research they shared with Humana had been authored by doctors with alleged financial relationships to the company, Humana cannot claim that it took this research at face value. The studies allegedly referred to in the meeting all *pre-date* the public reports discussed above and the promulgation of the BMP Policy. *Id.* It is therefore implausible that Humana was incapable of "discover[ing] the cause of action despite exercising reasonable care and diligence." *Pero's*, 90 S.W.3d at 625.

The upshot is that Humana's fraud-based claims[22] are either time-barred or fail to plausibly allege reliance because Humana knew or should have known all of the information necessary to plead its claims no later than mid-2009.[23] Indeed, if Humana's injury was that it paid for Infuse, then *all* of its fraud claims are barred. Likewise, since Humana's conversion claim depends on the same alleged misrepresentations, and is not subject to the discovery rule, any viable claim accrued more than two years outside the statutory limit.

III. IN ADDITION TO THE OVERARCHING FLAWS DISCUSSED ABOVE, EACH OF HUMANA'S CLAIMS SUFFERS FROM IRREMEDIABLE PLEADING DEFECTS.

A. Humana's Fraud-Based Allegations Fail to State a Claim for Relief.

Humana's FAC broadly alleges two theories of fraud. The first, discussed in detail *supra* at pp. 4–8, relates to claims for off-label Infuse procedures Humana knowingly paid in reliance on allegedly unreliable medical literature. The second relates to Humana's supposedly unwitting reimbursement for such procedures based on allegedly fraudulent claims that disguised the off-label use of Infuse. Humana's failure to plead an injury in fact traceable to Medtronic's conduct with respect to the former theory is jurisdictional and requires dismissal of all of the related claims. But both of Humana's theories also suffer from fatal pleading deficiencies that provide independent reasons for dismissal under Rule 12(b)(6).

Moreover, "[b]ecause claims based on fraud pose a high risk of abusive litigation," Humana "must state with particularity the circumstances constituting the fraud or mistake." *Republic Bank & Trust Co. v. Bear Stearns & Co., Inc.*, 683 F.3d 239, 247 (6th Cir. 2012)

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[22] These include Counts One, Two, Three, Four, Nine, and Ten. Medtronic assumes for the purposes of this Motion to Dismiss that Count Six is also based on a claim of fraud. *See supra* at pp. 4–8.

[23] Because Humana has insufficiently alleged its subrogation claims, it is impossible to tell when its insureds' claims, if any, were or should have been discovered. *See Jastrebski v. Smith & Nephew Richards, Inc.*, 1999 WL 144935, at *4 (Tenn. Ct. App. Mar. 18, 1999) (applying discovery rule in a medical device personal injury suit).

(internal citation and quotation marks omitted); *see* Fed. R. Civ. P. 9(b). The Sixth Circuit has "interpret[ed] Rule 9(b) as requiring plaintiffs to allege the time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud." *Cataldo v. U.S. Steel Corp.*, 676 F.3d 542, 551 (6th Cir. 2012) (internal quotation marks omitted) *cert. denied*, 133 S. Ct. 1239 (2013). And the plaintiff must "explain why the statements were fraudulent." *Heinrich v. Waiting Angels Adoption Svcs., Inc.*, 668 F.3d 393, 404 (6th Cir. 2012). Humana's allegations are plainly insufficient.

1. Humana's Allegations of Fraudulent Billing Practices Are Insufficiently Pled (Counts 1–4).

The most obvious shortcoming of Humana's fraudulent billing claims is the FAC's failure to identify a single claim for reimbursement that included a "false" or misleading billing code. Although Humana avers that it unearthed the use of fraudulent codes in a 2011 audit of spine surgeries, FAC ¶ 240, it cites no specific instance in which such a code was used. Under Humana's own theory, each claim related to off-label Infuse procedures that was submitted with a fraudulent code is a fraudulent statement, which must be identified with particularity. *Cataldo*, 676 F.3d at 551; *Heinrich*, 668 F.3d at 403 (applying standard to civil RICO claims). Humana's failure to meet that elementary standard here is inexplicable. If Humana *actually discovered* fraudulent claims, it cannot maintain that it is incapable of identifying them to this Court.

Holding Humana to Rule 9(b) is especially critical here since it is clear from the face of the FAC that the codes allegedly used are *not misleading* in themselves. *See* FAC ¶ 181. Humana's own reimbursement policy directs providers to use the codes in question in claims for bone graft substitutes like Infuse.[24] Claims that included such codes would therefore be

[24] *See* Ex. 8 (Bone Graft Substitutes, Medical Coverage Policy, Policy No.: CPLD–0479–002).

misleading—if at all—only if they omitted required information that would allow Humana to specifically identify off-label uses of Infuse. Rule 9(b) requires fraud plaintiffs to "explain *why* the statements were fraudulent." *Heinrich*, 668 F.3d at 404 (emphasis added). Humana cannot do that without first identifying the reimbursement claims at issue and explaining why they were not uncovered when Humana's duty to conduct a reasonable investigation attached in 2009. *See supra* at pp. 15–20.

And even if Humana could provide a list of allegedly fraudulent claims for reimbursement, and explain what rendered them misleading, its allegations fail for a more basic reason: the FAC fails to plausibly allege any fraudulent scheme or intent. Humana contends that Medtronic "sometimes discouraged" providers from reporting Infuse use. *Id.* ¶ 181. And it pleads "upon information and belief" that Medtronic "encouraged" doctors to use some codes and not others. *Id.* "While fraud may be pled on information and belief when the facts relating to the alleged fraud are peculiarly within the perpetrator's knowledge, the plaintiff must still set forth the factual basis for his belief." *U.S. ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 512 (6th Cir. 2007); *Sanderson v. HCA-the Healthcare Co.*, 447 F.3d 873, 878 (6th Cir. 2006) (stating that pleadings on information and belief "must not be mistaken for license to base claims of fraud on speculation and conclusory allegations"). Humana offers no factual basis for its belief that Medtronic micromanaged providers' billing practices; its "information and belief" pleading refers only to what it wishes it could substantiate.[25]

In short, Humana has not identified a single fraudulent claim, is unable to explain why a claim with the billing codes mentioned in the FAC would have been fraudulent, and offers no

[25] The same defect undermines Humana's claim that Medtronic discouraged providers from complying with Humana's requests for medical records necessary to process claims. FAC ¶ 178. In any case, if Humana chose to reimburse claims even after being refused access to documents necessary to determine whether the claim was reimbursable, it has only itself to blame.

basis for this Court to infer that Medtronic was involved in the choice of billing codes in the first place. The FAC does not allow Medtronic "fair notice" or "enable [it] to prepare an informed pleading responsive to [any] specific allegations of fraud" as required by Rule 9(b). *Bledsoe*, 501 F.3d at 504 (internal quotation marks omitted). Accordingly, the fraudulent billing allegations must be dismissed.

2. Humana's "Tainted Literature" Claims Fail to Plead Either Fraud or Reliance (Counts 1–4 and 6).

After spending 87 paragraphs rehashing publicly available allegations of Medtronic's purported influence over the medical literature, Humana admits that it never read *any* of that literature. FAC ¶¶ 52–139. Instead, Humana reviewed only third-party "summaries." *Id.* ¶ 146. The "tainted literature" claims thus gloss over two degrees of separation from Medtronic: Humana must show not only that the authors were somehow agents of Medtronic, but also that Medtronic expected that any statements the doctors supposedly made on its behalf would be conveyed to Humana. Moreover, Humana acknowledges that the summaries it read discussed publications described in just a fraction of the paragraphs that purport to lay that foundation. *Id.* ¶¶ 146–54. The allegations in the remaining paragraphs are simply irrelevant—according to the FAC itself—to any materials conveyed to Humana. And the supposedly relevant paragraphs do not allege any actionable misrepresentations at all. *See id.* ¶¶ 147–54.

Page-limit constraints prevent Medtronic from fully engaging with these deficiencies—which are in any case pertinent only if this Court overlooks Humana's failure to establish standing. But a few examples illustrate the point. Several of the "summaries" allegedly referred to materials described at ¶¶ 60–64. *See id.* ¶¶ 147–49, 153. The only "misrepresentation" alleged in ¶¶ 60 and 62 is the statement that testing revealed no "unanticipated device-related adverse events." Although Humana alleges in conclusory fashion these statements are "false," it does not allege that *no* adverse events were disclosed, and it makes no effort to plead any difference between the level of adverse events that *were* anticipated and those it claims actually occurred. Likewise, in ¶¶ 63–64, Humana claims that certain articles "failed to report adverse events . . . that should have been reported." *See also* ¶ 117. But these are nothing more than "naked assertion[s]," which are "not entitled to a presumption of truth" on a motion to dismiss. *Iqbal*, 129 S. Ct. at 1949. Finally, ¶ 61 doesn't allege any falsehood at all—it recites an editorial decision to emphasize information about traditional bone grafting. [26]

Even if the FAC did adequately identify actionable misrepresentations, Humana has alleged, at most, that it relied on purportedly "tainted" sources of medical information included in "summaries" published from December 2004 to September 2008. FAC ¶¶ 147, 151. Although Humana pleads that these sources are listed "[b]y way of example and not limitation," it cannot ignore the requirements of Rule 9(b). This Court cannot infer misrepresentations not specifically alleged in the pleadings. *See Bledsoe*, 501 F.3d at 509; *Bishop*, 520 F.3d at 522 & n.1.

Moreover, to plead fraud, Humana must show that it reasonably relied on the few alleged misrepresentations it claims to have read.[27] The reasonableness of Humana's reliance does not depend on whether it knew *why* the literature was (allegedly) unreliable—all that matters is that it knew or should have known *that* the literature was incorrect, unreliable or misleading.

[26] Many of the other alleged "misrepresentations" are nothing more than statements of opinion based on data Humana cannot contend was fraudulently created, *e.g.*, FAC ¶¶ 66–75, 106–111, 118–20, and which are therefore shielded by the First Amendment, *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 498 (2d Cir. 2013); *see Underwager v. Salter*, 22 F.3d 730, 736 (7th Cir. 1994) ("Scientific controversies must be settled by the methods of science rather than by the methods of litigation.") Others are asserted in an entirely conclusory manner. *E.g.*, FAC ¶ 105.

[27] *See Davis v. McGuigan*, 325 S.W.3d 149, 154 (Tenn. 2010) (fraudulent misrepresentation); *Power & Tel. Supply Co. v. SunTrust Banks, Inc.*, 447 F.3d 923, 931 (6th Cir. 2006) (intentional misrepresentation); *Chrisman v. Hill Home Dev., Inc.*, 978 S.W.2d 535, 538–39 (Tenn. 1998) (fraudulent concealment).

Although reliance is ordinarily a fact-bound question, *McGuigan*, 325 S.W.3d at 158, the pleadings here affirmatively negate any possibility of reasonable reliance after early 2009.[28] Humana alleges that it promulgated the BMP Policy, barring reimbursement for off-label uses of Infuse "based upon the balance of the literature (which then included more recent non-fraudulent articles *exposing the dangers and inefficacy* of highly expensive, off-label BMP uses) . . . ." FAC ¶ 163 (emphasis added). And Humana avers that the "BMP Policy has been reviewed . . . on an annual basis since 2009 and has *never been changed* . . . ." *Id.* ¶ 164 (emphasis added). In other words, by 2009, Humana had already made its own determination that the prior medical literature was unreliable—a determination it reaffirmed on an annual basis. It cannot have been reasonable for Humana to rely on literature it affirmatively alleges it believed was erroneous.[29] *Allied Sound, Inc. v. Neely*, 58 S.W.3d 119, 123 (Tenn. Ct. App. 2001) (reliance is not reasonable as matter of law where plaintiff is on inquiry notice of the alleged fraud).

Under these circumstances, it is audacious for Humana to suggest that it was fooled again in October 2010, when Medtronic's representatives allegedly showed it materials based on the same, pre-2008 articles Humana had already decided were not credible. *See id.* ¶¶ 169–172 (referring to materials citing articles dated 2002–05). Not only could Humana not reasonably have relied on any representations based on these materials, in view of its own conclusions about the pre-2008 research, but the fact that it never changed the BMP Policy it adopted in 2009 demonstrates that it was not in fact swayed.

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[28] Where a plaintiff attempts to establish reliance on a statement conveyed by a third person (in this case, the services that summarized medical literature for Humana, FAC ¶ 146), the plaintiff must show that it would have been reasonable for it to rely on the defendant's underlying statement, rather than on the intermediary's conveyance. *McGuigan*, 325 S.W.3d at 158–59.

[29] Without a plausible allegation of reliance, Humana cannot show that the alleged fraud was a proximate cause of some injury to its business. *See Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 457–58 (2006); *Holmes v. SIPC*, 503 U.S. 258, 271–73 (1992) (noting that the injury must be "direct"); 18 U.S.C. § 1964(c) (establishing civil remedies for substantive violations of the RICO statute). That leaves it without statutory standing to bring its RICO claims. Although a civil RICO plaintiff is not required to prove first-person reliance where fraud is the predicate act, *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 649–50 (2008), Humana's entire theory of this case is predicated on its reliance on either allegedly unreliable literature or fraudulent claims for reimbursement.

B. Humana's Consumer Protection Act Claims Fail the Elementary Requirements of Notice Pleading and Procedural Fairness (Count Six).

Without specifying where any of its providers submitted reimbursements for off-label Infuse procedures, Humana pleads a list of consumer protection statutes from all fifty states, the District of Columbia and Puerto Rico. Rule 8's requirement of "a short and plain statement of the claim showing that the pleader is entitled to relief," Fed. R. Civ. P. 8(a)(2), "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation," *Iqbal*, 129 S. Ct. at 1949 (internal quotation marks omitted); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).[30] Yet that is all Humana provides—it makes no effort to explain how it is entitled to relief under any, let alone all, of those statutes. It is not enough to allege that Humana's health-insurance plans "cover Members in all fifty States." FAC ¶ 140. Medtronic has a right to know where it is alleged to have *injured* Humana and under which laws it must prepare a defense. *Twombly*, 550 U.S. at 555 (a defendant is entitled to "fair notice of what the claim is and the grounds upon which it rests"). And it has a right to know *how* it is alleged to have violated the provisions of those laws.[31] This is shotgun pleading at its worst—a practice that federal trial courts have repeatedly condemned.[32]

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[30] Although Rule 8 alone requires dismissal of Humana's threadbare pleadings, many, if not all, of its consumer protection claims are subject to the more stringent requirements of Rule 9(b). *See, e.g.*, *LeBlanc v. Bank of Am., N.A.*, 2013 WL 3146829, at *6 (W.D. Tenn. June 18, 2013) (surveying Tennessee law and concluding that "TCPA claims are subject to the higher pleading standard articulated in Rule 9(b)"); *Duran v. Clover Club Foods Co.*, 616 F. Supp. 790, 793 (D. Colo. 1985) (holding that claims under the Colorado Consumer Protection Act are subject Rule 9(b)).

And the problem here is hardly academic; a cursory survey of the statutes cited in the FAC reveals that Humana's claims would be barred as a matter of law under at least a third of them. For example, many states impose pre-suit notice requirements on plaintiffs asserting consumer protection claims.[33] Humana has not alleged compliance with those requirements. In other states, insurers do not qualify as "consumers" with standing to bring claims.[34] And, as many courts have recognized, medical devices like Infuse are not "consumer goods" subject to those laws.[35] Medtronic cannot be required to mount a defense under the laws of fifty-two jurisdictions where Humana has made no attempt to connect Medtronic's conduct to any of them or to explain how that conduct violates even one of the statutes listed.

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[31] *See, e.g.*, *Harvey v. Ford Motor Credit Co.*, 1999 WL 486894, at *2 (Tenn. Ct. App. July 13, 1999) (affirming the dismissal of a Tennessee Consumer Protection Act claim where the plaintiff failed to "allege a causal connection between the defendant's conduct and any injury suffered"); *see also Oliveira v. Amoco Oil Co.*, 776 N.E.2d 151, 160 (Ill. 2002) (holding that a private plaintiff must plead causation in order to state a claim under the Illinois Consumer Fraud and Deceptive Business Practices Act).

[32] *See, e.g.*, *In re Trilegiant Corp.*, 11 F. Supp. 3d 82, 125 (D. Conn. 2014) (dismissing numerous state consumer protection act claims where the plaintiffs failed to "t[ie] the Defendants' alleged conduct to violations of these statutes" and holding that merely listing such statutes does not "me[e]t the pleading requirements of Rule 8(a)"); *Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 2d 508, 531 (D.N.J. 2011) (explaining that the "catch-all listing of [consumer protection] statutes does not meet the most basic pleading requirements") (internal quotations omitted); *Young v. Wells Fargo & Co.*, 671 F. Supp. 2d 1006, 1016 (S.D. Iowa 2009) ("Shotgun pleading is especially problematic with respect to pleading numerous causes of action under . . . state consumer protection statutes . . . .") (internal quotation marks omitted)

[33] *See, e.g.*, Miss. Code Ann. § 75-24-15(2) ("In any private action brought under this chapter, the plaintiff must have first made a reasonable attempt to resolve any claim through an informal dispute settlement program approved by the Attorney General."); *see also In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 84 (D. Mass. 2005) (listing Alabama, Alaska, California, Georgia, Indiana, Kansas, Maine, Massachusetts, Mississippi, Missouri, New Jersey, Oregon, Texas, Washington, and Wyoming as states that impose pre-suit notice requirements).

[34] *See, e.g.*, *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 WL 2043604, at *32 (D.N.J. July 10, 2009) (holding that third-party payors are not "consumers" under New Jersey's Consumer Fraud Act); *Scully Signal Co. v. Joyal*, 881 F. Supp. 727, 741 (D.R.I. 1995) (holding that corporations are not "consumers" under Rhode Island's Deceptive Trade Practices Act); *Blue Cross & Blue Shield of Ga., Inc. v. Kell*, 488 S.E.2d 735, 740 (Ga. Ct. App. 1997) (holding that "consumer" under the Georgia Fair Business Practices Act means a "natural person," not an insurer).

As with every other major flaw in its FAC, all of the information necessary to prepare a complete pleading—if it exists at all—is exclusively in Humana's hands. Medtronic sells its products to health care providers, not to insurers. Only Humana can tell this Court in which states its insureds sought reimbursement for Infuse. Its failure to do so a second time is fatal to its consumer protection claims. *See Bishop*, 520 F.3d at 522 (dismissal warranted where plaintiff fails to plead information in its possession necessary to substantiate its claims).

C. Humana Lacks a Private Right of Action to Bring Its Medicare Secondary Payor Claims (Counts Eleven–Fourteen.)[36]

All four of Humana's new counts are based on Medtronic's May 6, 2014 settlement of Infuse-related claims with "[a]t least one (and likely more)" of Humana's insureds. FAC ¶ 350. Humana claims that this individual—and possibly others—is a Medicare beneficiary and that Humana is therefore entitled under the Medicare statute, 42 U.S.C. § 1395, *et seq.*, to be reimbursed for any expenses it incurred in treating him or her for Infuse-related injuries.

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[35] *See, e.g.*, *White v. Wyeth*, 705 S.E.2d 828, 838 (W.Va. 2010) ("Prescription drug cases are not the type of private causes of action contemplated under the [statute] because the consumer can not and does not decide what product to purchase."); *Herzog v. Arthrocare Corp.*, 2003 WL 1785795, at *10 (D. Me. Mar. 21, 2003) (holding that medical devices do not qualify as "consumer goods" under Maine's Unfair Trade Practices Act); *see also Balderston v. Medtronic Sofamor Danek, Inc.*, 285 F.3d 238, 242 (3d Cir. 2002) (holding that because surgical screws are not for "personal use," the purchase of such screws by a physician was not actionable under Pennsylvania's Unfair Trade Practices and Consumer Protection Law).

[36] For purposes of this motion to dismiss, Medtronic necessarily accepts the FAC's factual allegations as true. But the key allegations underlying Humana's new claims are misleading. Perhaps most significantly, Medtronic's settlements include provisions requiring that all third-party liens—including any liens Humana may have by virtue of having paid for a claimant's Infuse-related medical treatment—be satisfied.

Because none of the provisions cited in the FAC provides Humana with a private right of action, the new counts must be dismissed.[37]

1. Overview

In order to "counteract escalating healthcare costs," Congress amended the Medicare statute in 1980 to include a cost-containment provision known as the Medicare Secondary Payor Act (the "MSP Act"). *Mich. Spine & Brain Surgeons, PLLC v. State Farm Mut. Auto. Ins. Co.*, 758 F.3d 787, 790 (6th Cir. 2014). The MSP Act provides that Medicare coverage is secondary to other coverage enjoyed by a Medicare beneficiary—that is, that any other applicable coverage or "primary plan" is applied first, before federally-funded Medicare benefits kick in. *See* 42 U.S.C. §1395y(b)(2)(A); *Manning v. Utils. Mut. Ins. Co., Inc.*, 254 F.3d 387, 396 (2d Cir. 2001). Humana alleges that Medtronic qualifies as a "primary plan" with respect to the settling claimant(s) under the Act because it is a self-insured product manufacturer and has settled tort claims with Medicare beneficiaries. FAC ¶¶ 341–44 (citing 42 U.S.C. §§ 1395y(b)(2)(A), (2)(B)(ii)).

The MSP Act contemplates that a Medicare beneficiary may sometimes require treatment before a primary plan can be expected to pay for it. When that happens, the Act authorizes the Secretary of Health and Human Services to make conditional payments covering the beneficiary's medical treatment and, if necessary, to bring an action against a primary plan to recover double the amount due. 42 U.S.C. §1395y(b)(2)(B). Humana does not allege that Medicare has made any payments on behalf of the settling claimant(s). Rather, Humana alleges that it is the assignee of claims held by certain Medicare Advantage Organizations ("MAOs").

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[37] Because Humana cannot establish a right to reimbursement from Medtronic or a private right of action under any of the provisions cited in the FAC, it cannot maintain its claim for declaratory judgment (Count 11). Its claim for an accounting (Count 14) fails for separate reasons, discussed *infra* at pp. 33–34.

See FAC ¶ 329. MAOs are private insurers authorized under Medicare Part C to provide access to private health-plan choices in addition to the standard fee-for-service federal Medicare plan choices. 42 U.S.C. § 1395w-21. They enjoy rights that are analogous to those of Medicare when it stands as a secondary payor, in that MAOs "may" "charge" a primary plan for services "in accordance with the charges allowed under a law, plan or policy." 42 U.S.C. § 1395w-22(a)(4). But Congress elected not to endow MAOs with any of the rights to reimbursement available to the government. *See Care Choices HMO v. Engstrom*, 330 F.3d 786, 790 (6th Cir. 2003) (noting that the statute provides "a fairly clear indication that Congress intended the Medicare program to have more extensive rights" than implied by the right to "charge").

2. The MSP Private Right of Action Does Not Provide Humana With a Claim Against Medtronic (Count 12).

To complement the government's authority to seek reimbursement from primary payors, the MSP Act "contains a private right of action to incentivize citizens to aid the government in recovering funds erroneously paid by Medicare." *Caldera v. Ins. Co. of Penn.*, 716 F.3d 861, 863 (5th Cir. 2013); 42 U.S.C. § 1395y(b)(3)(A) (the "MSP private right of action"). In *Manning*, the Second Circuit analogized the MSP private right of action provision to the False Claims Act, explaining that both statutes were intended to create "private attorneys general" to "sue in order to right an economic wrong *done to the government*." 254 F.3d at 394 (emphasis added).

Humana does not allege that Medicare made any contingent payments to the settling claimant(s). *Cf. Mich. Spine*, 758 F.3d at 788–89 (considering a suit brought by a provider partially reimbursed by a conditional payment from Medicare). Instead, Humana claims that the MSP private right of action encompasses actions to recover funds paid by *any* Medicare payor, including an MAO. *See* FAC ¶¶ 357–58. That argument is in tension with the reasoning of

Caldera and *Manning*, which understood the private right of action as a means to allow private citizens to vindicate the *government's* rights. It also ignores the text of the MSP Act, which predicates the private right of action on a primary payor's failure to make a primary payment "in accordance with" section 1395y(b)(2)(A). That section refers in turn to the *government's* authority to make conditional payments on behalf of a beneficiary. *See* 42 U.S.C. §§ 1395y(b)(2)(A), (B). Insofar as the MSP Act is intended to save taxpayer money, and the private right of action, like the False Claims Act, is intended to incentivize recovery on the government's behalf, that statutory structure makes sense. By contrast, because MAOs receive a fixed amount of money per beneficiary from the government each year, taxpayers pay the same amount whether the MAO recovers from a primary payor, or not. *See* 42 U.S.C. § 1395w-23. The policy reasons identified by the Second and Fifth Circuits would therefore not be served by allowing Humana's claims to proceed.

Humana refers in the FAC to a contrary position, taken by the Third Circuit. FAC ¶ 340 (citing *In re Avandia Marketing Sales Prac. & Prods. Liab. Litig.*, 685 F.3d 353 (3d Cir. 2012) *cert. denied*, 133 S. Ct. 1800 (2013)). The *Avandia* court concluded that the MSP private right of action "plac[es] no limitations upon which private (i.e., non-governmental) actors can bring suit." 685 F.3d at 359. But apart from some ambiguous legislative history, the court did not offer any reasoning to explain the ultimate effect of its decision, which was not only to allow an MAO to bring suit, but to allow it to bring suit in the absence of any conditional payment by the government.[38] *See id.* at 363–64.

[38] The court held in the alternative that an MAO's right to recover on its own behalf was supported by regulation. *Avandia*, 685 F.3d at 366. But it is axiomatic that "language in a regulation may invoke a private right of action that Congress through statutory text created, but it may not create a right that Congress has not." *Alexander v. Sandoval*, 532 U.S. 275, 291 (2001); *see also Parra v. PacifiCare of Ariz., Inc.*, 715 F.3d 1146, 1154 (9th Cir. 2013) (the MAO Regulation "adds nothing to a MAO's claim to a private right of action").

Avandia is, of course, not binding upon this Court. And the Third Circuit's decision has not been followed by other federal appellate courts. *See, e.g.*, *Parra*, 715 F.3d at 1154 (declining to decide "whether *Avandia* was decided correctly"). *Cf. Potts v. Rawlings Co., LLC*, 897 F. Supp. 2d 185, 197 (S.D.N.Y. 2012) (recognizing the conflict between *Avandia* and other federal court decisions). But more fundamentally, *Avandia* is unpersuasive in light of the reasoning in *Caldera* and *Manning* and the text of the MSP Act itself, *see* § 1395y(b)(2). Humana's claim should be dismissed.

3. Humana Has No Right to "Charge" Medtronic (Count 13).

Apparently in the alternative, Humana purports to "charge" Medtronic under Medicare Part C for medical services provided to Humana Medicare claimants with whom Medtronic has reached settlements. FAC ¶ 362; *see* 42 U.S.C. § 1395w-22(a)(4). But courts have repeatedly held that the provision authorizing MAOs to "charge" primary payors merely allows an MAO "to include in its insurance contract a right of subrogation against an insured's recovery from a third-party for money previously paid for the insured's medical care." *Ferlazzo v. 18th Ave. Hardware, Inc.*, 929 N.Y.S. 2d 690, 693 (N.Y. Supr. Ct. 2011); *accord Parra*, 715 F.3d at 1154; *Nott v. Aetna U.S. Healthcare, Inc.*, 303 F. Supp. 2d 565, 571–72 (E.D. Pa. 2004). The statute "does not expressly require a primary plan to reimburse a private insurer providing replacement coverage for Medicare-eligible persons or expressly authorize a private right of action in favor of the private insurer to recover payments." *Ferlazzo*, 929 N.Y.S. 2d at 692; *accord Estate of Ethridge v. Recovery Mgmt. Sys., Inc.*, 326 P.3d 297, 306 (Ariz. Ct. App. 2014). That is why federal and state courts have repeatedly held that MAOs have no private right of action against a primary payor under the Medicare Statute.[39]

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[39] *See, e.g.*, *Parra*, 715 F.3d at 1153; *Konig v. Yeshiva Imrei Chaim Viznitx of Boro Park Inc.*, 2012 WL 1078633, at *2 (E.D.N.Y. Mar. 30, 2012); *Nott*, 303 F. Supp. 2d at 571–77; *Estate of*

The Sixth Circuit has construed virtually identical language in a parallel provision with the same result. In *Care Choices*, the court of appeals interpreted a secondary payor provision applicable to privately run HMOs. *See* 42 U.S.C. § 1395mm(e)(4). Like the courts in *Ferlazzo* and *Estate of Ethridge*, the Sixth Circuit concluded that the statute only authorized HMOs "to create a right of reimbursement for themselves in the context of their own insurance agreements with Medicare beneficiaries." *Id*. at 789. The court contrasted the language in the "right to charge" provision with that used in the MSP Act, concluding that it provided "a fairly clear indication that Congress intended the Medicare program to have more extensive rights" in the MSP Act. *Id*. at 790.

The logic of *Care Choices* applies here and requires dismissal of Count 13. While Humana's subsidiaries could have contracted with their insureds for reimbursement out of any settlement proceeds, nothing in the "right to charge" provision of Part C authorizes Humana to proceed directly against Medtronic, and there is no evidence that Congress intended to grant such a right to MAOs.

4. Accounting Claim (Count 14)

Finally, Humana asks this Court to order an accounting on the basis of defenses and objections Humana "expects" Medtronic to make "once" it settles with third-party claimants. FAC ¶ 371. An accounting is "predicated upon the assumption that the party seeking relief does not have the means to determine how much—or, in fact, whether—any money properly his is being held by another." *Garcia v. Koch Oil Co. of Tex. Inc.*, 351 F.3d 636, 641 (5th Cir. 2003). It is not justified where civil discovery is adequate to determine the amount of liability. *See*

Ethridge, 326 P.3d at 301 ("Medicare Part C does not, by itself, require reimbursement or create a private right of action to pursue reimbursement"; *Trezza v. Trezza*, 957 N.Y.S. 2d 380, 386 (N.Y. Supr. Ct. 2012) ("[T]here is no statutory right to reimbursement in favor of Medicare Advantage insurers. . .").

Border State Bank, N.A. v. AgCountry Farm Credit Servs., 535 F.3d 779, 785 (8th Cir. 2008) (denial of accounting not error where plaintiff failed to show it could not obtain information through discovery). The Sixth Circuit has long recognized that the "the liberal discovery procedures of the Federal Rules" mean that legal remedies will ordinarily be "adequate"—and a resort to equity therefore precluded—even where the facts of a case are complex. *Bradshaw v. Thompson*, 454 F.2d 75, 79 (6th Cir. 1972); *see Digital 2000, Inc. v. Bear Commc'ns, Inc.*, 130 F. App'x 12, 23 (6th Cir. 2005) (noting that "[i]n light of the broad discovery available to litigants [in federal court], accounting actions are of dubious utility").

To the extent Humana's accounting claim is based on settlements Medtronic already has concluded with third-party claimants, there is no reason to think the facts and accounts are "so complex that adequate relief may not be obtained at law." FAC ¶ 370. Humana possesses all of the information necessary to determine how much it paid in treatment for any of its insureds, and any settlement documents will clearly indicate the amount paid out to any settling claimant.

CONCLUSION

For all of the foregoing reasons, Medtronic respectfully requests that this Court grant its motion to dismiss all counts of Humana's First Amended Complaint with prejudice.

Dated: December 5, 2014

Respectfully submitted,

s/Nathan A. Bicks

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CERTIFICATE OF SERVICE

I hereby certify that, on December 5, 2014, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will operate to provide notice of this filing to all counsel of record in this case.

s/Nathan A. Bicks
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